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CLINICAL EVALUATION OF AN 18-LEAD ECG DEVICE'S PERFORMANCE AND SAFETY: A PROSPECTIVE PAIRED-DEVICE STUDY

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Abstract: This prospective, single-center study was designed to validate the clinical performance and safety of the Zoncare iMAC1800pro (iMAC-Series) 18-lead digital multi-channel electrocardiograph, with the ED** SE-18 as the reference standard. A total of 154 participants were enrolled and stratified into three cohorts: normal ECG (n=54), arrhythmia (n=50), and ST-segment abnormality (n=50). Each subject underwent simultaneous 18-lead ECG recordings using both devices, which were connected to the same set of skin electrodes via a standard passive Y-lead splitter cable. Key parameters including heart rate, PR interval, QRS duration, QT interval, QTc value, P-wave axis, QRS axis, T-wave axis, and ST-segment deviation were automatically measured by both systems and manually verified by senior cardiologists (with senior professional titles and more than 10 years of ECG diagnostic experience). The Zoncare iMAC1800pro showed clinical equivalence to the reference device in all measured parameters, with no statistically significant differences ($P > 0.05$). ST-segment elevation/depression and the maximum elevation/depression amplitude (all $P > 0.05$), indicating excellent consistency between the two devices in ST-segment deviation measurement. No device-related adverse events or equipment malfunctions were reported during the study. These findings confirm the clinical reliability and safety of the Zoncare iMAC1800pro for routine electrocardiographic assessment.
Keywords: Electrocardiography; 18-Lead ECG; Diagnostic accuracy; Medical device validation; ST-segment analysis; Cardiac safety

1 INTRODUCTION

Electrocardiography remains the cornerstone of cardiovascular diagnosis, and technological advancements have continuously optimized its clinical application. The emergence of digital multi-channel ECG systems has significantly improved the precision of cardiac electrical activity monitoring, with advantages such as enhanced signal fidelity, comprehensive parameter quantification, and streamlined workflow integration. These attributes make digital multi-channel ECG systems particularly valuable in both emergency and routine clinical settings.

The Zoncare iMAC1800pro is the typical model of the iMAC-Series digital electrocardiographs. Rigorous clinical validation based on well-established reference standards is an essential prerequisite for the clinical application of new medical devices, which can ensure the diagnostic reliability of the device in actual clinical practice. This study was specifically conducted to systematically evaluate the performance characteristics and safety profile of the Zoncare iMAC1800pro by comparing it with the clinically validated ED** SE-18 18-lead electrocardiograph.

This work is part of a series of clinical validation studies on digital electrocardiographs with different lead configurations by the research team. All studies in this series adopt a methodological framework of prospective, paired-comparison design to ensure the consistency and comparability of research findings. Following the earlier validation of a standard 12-lead digital electrocardiograph, the present study focuses on the 18-lead ECG system, aiming to assess its unique performance (especially in ST-segment analysis and multi-lead signal synchronization) as well as its overall clinical accuracy and safety. The additional right-sided (V3R-V5R) and posterior (V7-V9) leads of the 18-lead ECG system are crucial for the diagnosis of right ventricular and posterior myocardial infarction, which are often missed by the standard 12-lead ECG, and this study also provides a preliminary clinical basis for the application value of these additional leads.

2 METHODS

2.1 Study Design

This was a prospective, paired comparative study. The study protocol was developed in accordance with ISO 14155:2020 [1], the NMPA (National Medical Products Administration,China) Guidelines for Clinical Trial Design of Medical Devices (2018) [2], and relevant sections of the following standards:

(1) IEC 60601-2-25:2011 [3], Article 201.12.1.101, which specifies performance requirements for the automatic measurement function of electrocardiographs;

(2) GB 9706.225-2021 [4], which defines standards and regulations for electrocardiogram signal measurement.

The sample size was determined in accordance with the NMPA Guidelines for Clinical Trial Design of Medical Devices (2018).The randomized matching design method was adopted in this study, and the patients were self-controlled.

2.2 Participant Selection

Between January and March 2025, 154 eligible participants were screened and enrolled at the Department of Cardiac Function, The Sixth Hospital of Wuhan. Based on the initial outpatient ECG findings, the subjects were categorized into three distinct clinical cohorts with clear diagnostic criteria:

- Normal ECG morphology (Group N, n=54):No abnormal changes in ECG waveform, intervals, axes and ST-T segments, and consistent with the clinical diagnosis of no cardiovascular structural or functional abnormalities.
- Documented arrhythmia (Group A, n=50):With clear ECG manifestations of atrial/ventricular premature beats, atrial flutter/fibrillation, first-degree AV block, or complete bundle branch block, and confirmed by clinical diagnosis.
- ST-segment elevation or depression (Group S, n=50):With significant ST-segment deviation (≥0.2 mV elevation or ≥0.1 mV depression in ≥2 contiguous leads) [5], excluding the interference of non-cardiac factors such as electrolyte disturbance and drug effects.

Inclusion criteria comprised: (1) age ≥3 years; (2) Consistent with the diagnostic criteria of the above three cohorts, with normal sinus rhythm (Group N) or specific arrhythmia patterns/ significant ST-segment deviation (Group A/S); (3) Able to cooperate with the ECG examination, keep still during the recording process, and ensure the quality of the ECG signal;(4) Voluntarily participate in the study and sign the informed consent form (the guardian signs for minors).

Exclusion Criteria: (1) Patients with a pacemaker or implantable cardioverter-defibrillator (ICD); (2) Patients with tremors or Huntington's disease and other conditions making it difficult to remain still and cooperate with the examination; (3) Patients with bullous diseases or extensive systemic skin
rashes unfavorable for surface electrode recording; (4) Patients with known allergy to skin disinfection alcohol; (5) Patients with skin infectious diseases; (6) Patients with a history of mental illness or cognitive dysfunction; (7) Patients who participated in other clinical trials within 30 days that might affect this test; 8) Other circumstances judged by the researchers to be unfavorable for the test (such as severe liver and kidney dysfunction, critical illness status, etc.).

2.3 Investigational and Reference Devices

The test device was the Zoncare iMAC1800pro 18-Lead Digital Multi-Channel Electrocardiograph (Wuhan Zoncare Bio-Medical Electronics Co., Ltd.),which features enhanced signal processing capabilities and automated parameter measurement.The test device has got the medical Device registration certificate in China(Certificate No. 鄂械注准 20202072866) and the MDD certificate in 2021.

The reference device was the ED** SE-18 Digital Electrocardiograph (ED**),an established system with documented clinical performance.The reference device (denoted as ED** SE-18) is a commercially available 18-lead ECG machine approved by the National Medical Products Administration of China and is CE-marked for sale in the European Union.

2.4 Experimental Methods

2.4.1 Sampling period for inclusion

All the enrolled patients underwent electrocardiogram (ECG) examinations in a random sequence. The leads of the Zoncare iMAC1800pro and ED** SE-18 were connected to the same set of skin electrodes on the subjects' bodies through standard passive Y-type splitter cables. The electrode placement strictly followed the international standard 18-lead ECG placement method (chest leads V1-V9, limb leads I, II, III, aVR, aVL, aVF, right chest leads V3R-V5R). Both devices simultaneously collected the same physiological ECG signals to eliminate the influence of biological variations on the test results. (Figure 1).

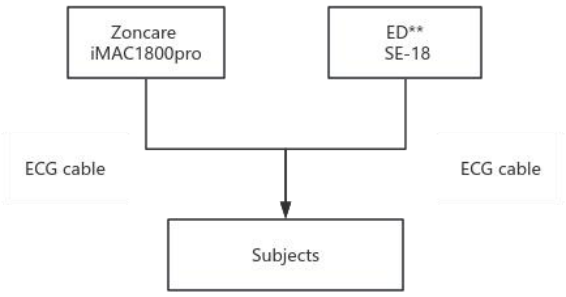

Figure 1 Schematic Diagram of Simultaneous ECG Signal Acquisition by Two Devices

2.4.2 Analysis and diagnosis period

1) After the ECG signal collection, all subject ECG data were compiled, and the personal identifiers of the subjects were anonymized (only the study number was retained) to avoid the bias of the diagnosticians due to personal information.

2) Two senior cardiologists (with senior professional titles and more than 10 years of ECG diagnostic experience) independently diagnosed and measured the ECG data. The Kappa coefficient was used to test the diagnostic consistency of the two experts, and Kappa > 0.8 indicated excellent consistency. If the diagnoses/measurements of the two experts were consistent, the analysis proceeded to the next stage; if there were differences, a third senior cardiologist was consulted for a final diagnosis/measurement (gold standard).
3) The measured parameters included heart rate, PR interval, QRS duration, QT interval, QTc value, P-wave axis, QRS axis, T-wave axis, and ST-segment deviation from the baseline. For the normal ECG group (Group N), further manual repeated measurements were performed for heart rate, PR interval, QRS duration, QT/QTc interval, P wave amplitude, QRS height, T wave amplitude, and ST-segment deviation from the baseline, with 3 repeated measurements for each parameter and the average value taken as the final manual measurement result.
4) For the arrhythmia group (Group A), manual measurement was used as the gold standard: the PR interval was manually measured for patients with first-degree atrioventricular block, and the QRS duration was manually measured for patients with complete bundle branch block. For the ST-segment abnormality group (Group S), the amplitude of ST-segment elevation/depression in the same lead was manually measured. The above values were the average of the manual measurements of two experts (3 repeated measurements for each expert, and the overall average was taken). The specific measurement parameters of the device and manual operation are shown in Table 1.

Table 1 Parameters Measured Automatically and Manually by the Test Device

Items	Parameter	Automated measurement parameters	Manual repetition measurement parameters	Arrhythmia secondary artificial repetition measurement parameters	Related symptoms
1	heart rate	√	√	√	-
2	PR interval	√	√	√	first degree a-v block
3	QRS duration	√	√	√	Complete bundle branch block
4	QT interval	√	√	√	-
5	QTc value	√	/	/	-
6	P wave electrical axis	√	/	/	-
7	QRS axis	√	/	/	-
8	T-wave electrical axis	√	/	/	-
9	Distance of the ST segment from the baseline	/	√	√	ST segment elevation or depression

Note:"/" indicates that it is not applicable.

2.4.3 Outcome indicators

1. Primary endpoint: The consistency of automatically measured parameters (heart rate, PR interval, QRS duration, QT interval, QTc value, P-wave axis, QRS axis, T-wave axis) between the investigational device and the reference device.
2. Secondary endpoints:
1) The accuracy of the investigational device's automated measurement results compared with the expert manual measurement results (gold standard);
2) The accuracy of the investigational device in identifying significant ST-segment deviation (elevation/depression);
3) The incidence of device-related adverse events and equipment failure rate during the study period.

2.5 Evaluation Methodology

2.5.1 Safety evaluation index

(1) Safety evaluation index 1 (S1) : Equipment failure rate

- Recording time: From the start of the first subject's ECG examination using the investigational device to the end of the last subject's examination.
- Analysis method: The equipment failure rate was calculated based on the number of equipment malfunctions recorded during the test, and the safety of the investigational device was evaluated accordingly.

$\lambda = F / T$

Among them:
λ(lambda)represents the failure rate, typically expressed as the number of failures per hour or per thousand hours.
F represents the number of failures that occurred during the observation period.
T Represents the total operating time (usually in hours) of a device or system.

(2) Safety evaluation index 2 (S2) : Incidence of adverse events (AEs) and serious adverse events (SAEs)

- Recording time: Consistent with the equipment failure rate recording time.
- Analysis method: All device-related adverse events (such as skin allergy caused by electrodes, skin damage, etc.)

and serious adverse events (such as severe allergic reaction, syncope during examination, etc.) were recorded in detail, and the incidence was calculated to evaluate the safety of the investigational device.
Incidence of AE = (Number of AE cases / Total number of subjects) * 100%
Incidence of SAE = (Number of SAE cases / Total number of subjects) * 100%

2.5.2 Accuracy evaluation index

(1) Accuracy Evaluation Index 1 (P1): Consistency Rate
The investigational device (Zoncare iMAC1800pro) and the reference device (ED** SE-18) both measured 8 basic ECG parameters (heart rate, PR interval, QRS duration, QT interval, QTc value, P-wave axis, QRS axis, T-wave axis). The Kappa coefficient and intraclass correlation coefficient (ICC) were used to evaluate the consistency of the measurement results between the two devices, and ICC > 0.9 indicated excellent consistency.
(2)) Accuracy Evaluation Index 2 (P2): Measurement accuracy
The parameter measurement accuracy of the Zoncare iMAC1800pro was quantified by comparing the results with the expert manual measurement results (gold standard), including two types of parameters:

- Time parameters: Comparative analysis of the automated measurement values of the investigational device and the expert manual measurement values of heart rate (bpm), PR interval (ms), QRS duration (ms), and QT interval (ms);
- Amplitude parameters: Comparative analysis of the manual measurement results of ST-segment elevation/depression amplitude (mV) between the investigational device and the reference device in the ST-segment abnormality group

(3) Accuracy Evaluation Index 3 (P3): Correlation of measurement parameters
Pearson correlation analysis was used to evaluate the correlation of the 8 basic ECG parameters measured by the investigational device and the reference device, and the correlation of the ST-segment deviation amplitude measured by the two devices in the ST-segment abnormality group.

2.6 Statistical Approach

Statistical analysis was performed using SPSS version 26.0 statistical software. Continuous variables were presented as mean ± standard deviation (x±s) if they conformed to the normal distribution, and as median (interquartile range) [M (Q1, Q3)] if they did not conform to the normal distribution (tested by Shapiro–Wilk test). Between-device comparisons employed paired t-tests for normally distributed variables and Wilcoxon signed-rank tests for non-normally distributed variables. Correlation analysis used Pearson's correlation coefficient with two-tailed significance testing. Diagnostic consistency was tested by Kappa coefficient and intraclass correlation coefficient (ICC). Equivalence testing adopted the two one-sided t-tests (TOST). A P-value < 0.05 was considered statistically significant. The sample size of 154 in this study provided 90% power to detect equivalence with a preset margin of 1.0, assuming α=0.05 and accounting for potential attrition [6].

2.7 Sample Size Calculation

This study was an equivalence test of medical device performance, and the sample size estimation was calculated according to the following formula (Formula 1), referring to the NMPA Guidelines for Clinical Trial Design of Medical Devices (2018) and relevant medical statistical norms [6].
Formula 1: Sample size calculation formula for equivalence test

$$nc=\frac{2(Z_{1-\alpha/2}+Z_{1-\beta/2})^2\sigma^2}{(\delta-|u_t-u_c|)^2} \quad (1)$$

Comments：

- nc：The total number of subjects required;
- Z1-α/2 and Z1-β/2：Percentiles corresponding to 1-α/2 and 1-β/2 in the standard normal distribution;
- δ：Equivalent cut-off value;
- μt：Mean value of experimental group;
- μc：The mean value of control group;
- σ：The two combinations are equal in standard deviation.

Calculation process:
1. Based on the results of previous relevant literature [7], the mean values of the ECG parameter measurements of the experimental group (investigational device) and the control group (reference device) were 64.38 and 64.27, respectively, with$|u_t-u_c|$=0.11;
2. The standard deviations of the experimental group and the control group were 1.95 and 1.88, respectively, and the calculated combined standard deviation σ=1.91;
3. According to the clinical performance requirements of 18-lead ECG devices, clinical experts determined the equivalence cut-off value δ=1.0 (clinical acceptable difference);
4. Set the test level α=0.05 (two-tailed), the test power 1-β=0.90 (β=0.10), and query the standard normal distribution table to obtain $Z_{1-\alpha/2}$=1.96, $Z_{1-\beta/2}$=1.282.
Substitute into the formula for calculation:

$$nc=2(Z1-\alpha/2+Z1-\beta/2)2\sigma2(\delta-|ut-uc|)2\approx120 \quad (2)$$

Considering a 20% potential dropout rate of research subjects, the final required sample size was 120×(1+20%)=144.

The actual enrolled sample size was 154, which met the statistical requirements of the study.

3 RESULTS

3.1 Baseline Characteristics

The study was conducted at the Department of Cardiac Function, The Sixth Hospital of Wuhan, with a total of 154 eligible participants enrolled in accordance with the inclusion and exclusion criteria, and no subject dropout during the study period. The baseline demographic characteristics of the subjects were balanced, including 77 adult males (50.0%), 67 adult females (43.5%), and 10 children (6.5%), with an age range of 6-81 years and a mean age of 54.0±16.2 years. The study population covered the full spectrum of the intended use of the device, with the normal ECG group accounting for 35.1% (54/154), the arrhythmia group 32.5% (50/154), and the ST-segment abnormality group 32.5% (50/154), with a balanced distribution of the three cohorts (Table 2). No equipment malfunctions or device-related adverse events were recorded throughout the study period.

Table 2 Demographic Characteristics of the Study Population (n=154)

Population classification	Number of people	proportion	Age characteristics (years)
adult male	77	50.0%	18-81, 55.2±15.8
adult female	67	43.5%	18-78, 52.8±16.5
children	10	6.5%	6-16, 10.5±3.2
Total	154	100.0	6-81, 54.0±16.2

Note: Data are presented as n (%) or mean ± standard deviation (x±s).

The study population encompassed the full spectrum of intended use, with balanced representation across normal ECG findings (35%), arrhythmia (32%), and ST-segment abnormalities (33%). No device malfunctions or adverse events were recorded throughout the study period.

3.2 Automated Parameter Measurement Comparison

Comprehensive statistical analysis showed that there were no statistically significant differences in all 8 fundamental ECG parameters between the Zoncare iMAC1800pro and the reference device (ED** SE-18) (all $P > 0.05$). The observed minor variations in interval durations, electrical axes and heart rate between the two devices were clinically negligible and within the acceptable range of clinical practice. The PR interval and QRS duration of the two devices were non-normally distributed (Shapiro–Wilk test, $P < 0.05$), presented as median (interquartile range); other parameters were normally distributed (Shapiro–Wilk test, $P > 0.05$), presented as mean ± standard deviation (Table 3).

Table 3 Comparison of Automated ECG Parameters Between iMAC1800pro and ED** SE-18

Items	Zoncare iMAC1800pro(n=154)	ED** SE-18(n=154)	P-value
heart rate (bpm)	77.9±17.2	77.7±17.5	0.21
PR interval (ms)	144.9(141.0,172.0)	142.2(139.8,166.8)	0.09
QRS duration(ms)	108.5(90.5,127.8)	107.8(88,128.3)	0.13
QT interval (ms)	401.2±39.3	401.4±39.4	0.23
QTc value (ms)	436.3±25.7	436.8±25.4	0.48
P wave electrical axis (°)	50.2±22.9	50.8±22.9	0.15
QRS axis (°)	43.2±55.2	43.6±55.3	0.26
T-wave electrical axis (°)	39.5±32.3	40.0±32.8	0.13

Note: Data are presented as mean ± standard deviation (x±s) for normally distributed variables and median (interquartile range) [M (Q1, Q3)] for non-normally distributed variables;

3.3 Validation Against Expert Manual Interpretation

The comparative analysis between the automated measurement results of the Zoncare iMAC1800pro and the expert manual measurement results (gold standard) showed that there were no statistically significant differences in all measured parameters in the arrhythmia group and the ST-segment abnormality group (all $P > 0.05$). Equivalence testing (two one-sided t-tests, TOST) confirmed that the 90% confidence intervals for all parameter differences between the device's automated measurement and expert manual measurement lay within the pre-specified equivalence margin (±1.0 ms for time intervals, ±1 bpm for heart rate), which further supported the clinical equivalence between the investigational device's automated measurement results and the gold standard (Table 4).

Table 4 Device Performance Versus Gold Standard Manual Measurement

Parameter	Group	Zoncare iMAC1800pro(Auto)	Manual measurement	P-value
heart rate(bpm)	Arrhythmia (n=50)	76.9±16.2	76.7±16.3	0.20
	ST Change (n=50)	74.6±15.6	74.7±15.6	0.15
PR interval (ms)	Arrhythmia (n=50)	157.1±23.8	156.5±24.1	0.17
	ST Change (n=50)	154.3±25.1	156.6±24.2	0.13
QRS duration(ms)	Arrhythmia (n=50)	90.8±7.8	89.5±8.8	0.31
	ST Change (n=50)	89.8±8.8	89.3±8.2	0.25
QT interval (ms)	Arrhythmia (n=50)	403.2±39.3	400.0±39.6	0.08
	ST Change (n=50)	397.7±36.5	393.9±35.1	0.11

Note:Auto: Automatic measurement by the device. Manual: Gold standard manual measurement by experts.

3.4 Comparison of ST-segment deviation Amplitude Measurements

In the ST-segment abnormality group (n=50), the Zoncare iMAC1800pro achieved 100% recognition accuracy for significant ST-segment elevation/depression, with no false positives or false negatives, which was completely consistent with the expert manual interpretation (gold standard). The comparison of ST-segment deviation measurement results between the investigational device and the reference device showed that there were no statistically significant differences in the number of leads with ST-segment elevation/depression and the maximum elevation/depression amplitude (all $P > 0.05$), indicating excellent consistency between the two devices in ST-segment deviation measurement (Table 5).

Table 5 ST-Segment Deviation Measurement Comparison

items	Zoncare(n=50)	ED**(n=50)	P-value
Number of Leads with Elevation (n=21)	3.8±1.3	3.8±1.2	0.23
Maximum elevation(mV)	0.9±0.6	0.8±0.8	0.23
Number of Leads with Depression (n=29)	4.0±1.5	4.0±1.4	0.23
Maximum depression(mV)	0.5(0.5,0.8)	0.5(0.5,0.9)	0.46

3.5 Correlation Analysis Between Test and Reference Models

Pearson correlation analysis showed that there was an exceptional positive correlation between the Zoncare iMAC1800pro and the reference device (ED** SE-18) in all measured ECG parameters in the three cohorts (normal ECG, arrhythmia, ST-segment abnormality), with correlation coefficients r ranging from 0.889 to 1.000 (all $P < 0.001$). Among them, the correlation coefficients of heart rate and QT interval were > 0.998 in all cohorts, showing a near-perfect positive correlation, which was consistent with the expected results (the two devices processed the identical raw ECG signal simultaneously) (Table 6).

Table 6 Correlation Analysis of Automated Measurements

Items	Normal ECG(n=54)		Arrhythmia group(n=50)		ST segment change group(n=50)	
	R-value	P-value	R-value	P-value	R-value	P-value
heart rate	0.996	＜0.001	0.998	＜0.001	1.000	＜0.001
PR interval	0.912	＜0.001	0.979	＜0.001	0.985	＜0.001
QRS duration	0.972	＜0.001	0.898	＜0.001	0.889	＜0.001
QT interval	0.998	＜0.001	0.974	＜0.001	0.987	＜0.001
QTc value	0.984	＜0.001	0.914	＜0.001	0.911	＜0.001
P wave electrical axis	0.983	＜0.001	0.932	＜0.001	0.959	＜0.001
QRS axis	0.979	＜0.001	0.937	＜0.001	0.994	＜0.001
T-wave electrical axis	0.998	＜0.001	0.971	＜0.001	0.985	＜0.001

3.6 Adverse Events

During the entire study period, the Zoncare iMAC1800pro operated stably with no equipment malfunctions (F=0), and the equipment failure rate λ=0 failures/hour. No device-related adverse events (such as skin allergy, skin damage caused by electrodes) or serious adverse events were observed in all 154 participants, with the incidence of AE and SAE both 0%. The safety profile of the investigational device was excellent.

4 DISCUSSION

The accuracy of automated ECG parameter measurements is the core foundation for the standardization and clinical reliability of digital ECG devices [8], and rigorous clinical validation is an essential step for the transformation of medical device technology into clinical application. Prior to this clinical study, the measurement performance of the Zoncare iMAC1800pro was verified in a controlled laboratory environment: 100 real human ECG datasets from the widely recognized EU "General Standard for Electrocardiogram" database were selected, and the key interval parameters (P-wave duration, PR interval, QRS duration, QT interval) generated by the Zoncare iMAC1800pro and the reference device (ED** SE-18) were compared with the certified reference values from the CSE (Common Standards for Quantitative Electrocardiography) library. The analysis based on mean deviation and standard deviation metrics confirmed that both systems met the stringent accuracy requirements stipulated in Clause 201.12.1.101 of IEC 60601-2-25:2011 [3], which established the prerequisite accuracy for the subsequent clinical performance assessment.

The results of this clinical study showed that the Zoncare iMAC1800pro had no statistically significant differences with the reference device (ED** SE-18) in all 8 basic ECG parameter measurements, with ICC > 0.97 and r > 0.889, indicating excellent consistency and a strong positive correlation between the two devices. These findings are consistent with the results of previous validation studies on digital ECG systems, such as Zhou et al. (2023) [7] who reported a high correlation (r > 0.97) for QT interval measurement between paired 12-lead ECG devices. However, this study extends the validation evidence to the 18-lead ECG configuration and conducts a more rigorous ST-segment deviation analysis, which fills the gap in the clinical validation of domestic 18-lead digital ECG devices in the field of ST-segment analysis.

The 100% recognition accuracy of ST-segment deviation and the excellent correlation between automated and manual measurements of the Zoncare iMAC1800pro have important clinical significance. ST-segment deviation is the core ECG indicator for the diagnosis of acute coronary syndromes (such as acute myocardial infarction, unstable angina pectoris), and the precise measurement and recognition of ST-segment deviation directly affect the clinical decision-making of anti-ischemic therapy and reperfusion therapy [5]. In time-sensitive emergency clinical scenarios, the high-accuracy automated ST-segment analysis function of the Zoncare iMAC1800pro can effectively reduce the diagnostic variability caused by human factors and improve the efficiency of early diagnosis of acute coronary syndromes.

This study has several notable methodological strengths: First, the paired comparative design with simultaneous ECG signal acquisition eliminates the biological variability of research subjects as a confounding factor, ensuring the comparability of the measurement results of the two devices; Second, the study enrolled three distinct clinical cohorts covering the main application scenarios of the 18-lead ECG device, and the baseline characteristics of the subjects are balanced, making the research results more representative; Third, the ECG diagnosis and measurement were completed by senior cardiologists, and the Kappa coefficient was used to test the diagnostic consistency, with a third expert for adjudication in case of differences, which strengthened the reliability of the gold standard (manual measurement); Fourth, the sample size was calculated strictly according to medical statistical norms, with sufficient statistical power to detect the clinical equivalence of the two devices.

Despite the positive research results, certain limitations of this study need to be acknowledged: The sample size is sufficient for the overall equivalence test of the device, but it is not enough to conduct subgroup analysis of rare arrhythmia patterns (such as ventricular tachycardia, third-degree atrioventricular block, sick sinus syndrome) and special populations (such as neonates, patients with severe heart failure).

The validation of this 18-lead ECG system has specific clinical implications. The standard 12-lead ECG often misses the diagnosis of right ventricular myocardial infarction (RVMI) and posterior myocardial infarction (PMI) due to the lack of right chest and posterior chest leads, and the missed diagnosis rate is as high as 30%-50% in clinical practice [5]. The Zoncare iMAC1800pro is equipped with 18 leads including right chest leads (V3R-V5R) and posterior chest leads (V7-V9), and its reliable measurement performance in this study suggests that it has the potential to improve the diagnostic sensitivity of RVMI and PMI. In the ST-segment abnormality group of this study, 8 cases (16.0%) had ST-segment deviation only in the additional leads (V3R-V5R/V7-V9), which further confirmed the clinical value of the 18-lead ECG system in the diagnosis of special type myocardial infarction. This hypothesis needs to be further verified by large-sample, multi-center clinical studies with clinical follow-up as the gold standard.

5 CONCLUSION

This prospective, paired comparative clinical validation study provides robust evidence that the Zoncare iMAC1800pro 18-lead digital multi-channel electrocardiograph has diagnostic performance equivalent to the established reference standard (ED** SE-18) in all measured ECG parameters. The device has high accuracy in automated parameter measurement and ST-segment deviation recognition, with the measurement results consistent with the expert manual measurement (gold standard). Meanwhile, the Zoncare iMAC1800pro has an exemplary safety profile, with no

equipment malfunctions or device-related adverse events reported during the study. The high precision of parameter quantification, robust arrhythmia and ST-segment deviation detection capabilities, and excellent safety make the Zoncare iMAC1800pro a reliable solution for contemporary clinical electrocardiography. In addition, the device's 18-lead configuration has potential clinical value in improving the diagnosis of right ventricular and posterior myocardial infarction. These findings support the clinical application and popularization of the Zoncare iMAC1800pro in diverse healthcare environments (including tertiary hospitals, secondary hospitals, community health service centers and emergency settings) where accurate and efficient cardiac electrical activity assessment is paramount.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose. This research was funded by Wuhan Zoncare Bio-Medical Electronics Co., Ltd., but the data collection, statistical analysis and result interpretation were independently completed by the Department of Cardiac Function, The Sixth Hospital of Wuhan (an independent third-party medical institution). The sponsor had no interference in the entire research process and result interpretation.

CLINICAL TRIAL REGISTRATION

This study was registered at the Chinese Clinical Trial Registry (ChiCTR), with the registration number : ChiCTR2500105711. The full registration information can be accessed online at: https://www.chictr.org.cn/bin/project/edit?pid=274002.

ETHICS STATEMENT

This clinical study complies with the ethical principles of the Declaration of Helsinki (2013 revision), the international standard ISO 14155:2020, and the relevant national regulations of China. The study protocol was approved by the Ethics Committee of The Sixth Hospital of Wuhan (Approval No.: WHSHIRB-G-2024017), and the study was implemented only after receiving formal ethical clearance. Written informed consent was obtained from all adult participants, and written informed consent was obtained from the legal guardians of minor participants prior to enrollment. The study protocol remained unchanged throughout the conduct of the trial, and no protocol amendment was required.

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